



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 10/566,752   | 02/01/2006  | James B. Jaquith     | 126-PCT2-US                  | 5932             |
| 49580  | 7590        | 06/20/2008           |                              |                  |
| PHILIP SWAIN, PHD<br>C/O GOWLING LAFLEUR HENDERSON<br>1 PLACE VILLE MARIE,<br>37TH FLOOR<br>MONTREAL, QC H3B 3P4<br>CANADA |             |                      | EXAMINER<br>HAYLIN, ROBERT H |                  |
|  |             |                      | ART UNIT                     | PAPER NUMBER     |
|  |             |                      | 1626                         |                  |
|  |             |                      | MAIL DATE                    | DELIVERY MODE    |
|  |             |                      | 06/20/2008                   | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/566,752

**Applicant(s)**

JAQUITH ET AL.

**Examiner**

ROBERT HAVLIN

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-49 and 52-63 is/are pending in the application.
- 4a) Of the above claim(s) 37, 41, 42, 47 and 53-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-36, 38-40, 43-46, 48-49, and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

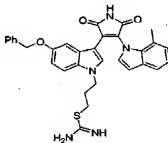
### DETAILED ACTION

**Status of the claims:** Claims 31-49, 52-63 are currently pending. Claims 1-30, 50, and 51 were cancelled. Claim 31 was amended.

**Priority:** This application is a 371 of PCT/CA04/01484 (08/11/2004). The certified copy of the priority document is not part of the application file and the conditions for claiming priority as described in the MPEP and PCT rule 17.1 are not met. Although the applicant states the "Notice of Acceptance" indicates the priority document was filed, it is currently not of record and the examiner believes the "Notice of Acceptance" erroneously indicated the documents filed.

### *Election/Restriction*

Applicant previously elected group I and the following species (compound 149



from previously cancelled claim 20): . Because no generic claim was found allowable (as demonstrated by the following rejections), the claims are restricted to the scope of ONLY the elected species and the following claims not reading on the elected species are held withdrawn: claims 37, 41, 42, 47, and 53-63.

### NEW CLAIM REJECTIONS

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1626

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added proviso to the claims is not supported by the specification, nor was it a part of the original claims. The following proviso is considered new matter:

with the proviso that when X<sup>1</sup>-X<sup>3</sup> are all C, R<sup>1</sup>-R<sup>3</sup> are all H, X<sup>4</sup> is CH, X<sup>5</sup> is C, R<sup>5</sup> is H, X<sup>10</sup> is CH, X<sup>6</sup>-X<sup>8</sup> are all C, R<sup>6</sup>-R<sup>8</sup> are all H, and X<sup>9</sup> is CH, then R<sup>4</sup> is not CH<sub>3</sub>.

### ***Claim Rejections - 35 USC § 103***

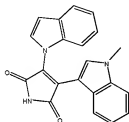
1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 31-36, 38-40, 43-46, 48-49, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US 5,057,614).

Art Unit: 1626

Davis et al. (US 5,057,614) on column 23, example 46 teaches the compound:



3-((1-indolyl)-4-(1-methyl-3-indolyl)-1H-pyrazole-2,5-dione, in addition the reference also teaches pharmaceutical

compositions thereof in claim 11, for example.

The instant claims read on a homolog of the above compound with an ethyl substitution instead of the methyl substitution on the 3-indolyl ring or an isomer with the methyl group at the 2-methyl position of the 3-indolyl ring.

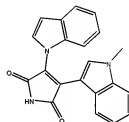
**MPEP 2144.09:** Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH<sub>2</sub>- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers *prima facie* obvious).

Thus, as stated in the relevant part of the MPEP above, because Davis teaches the methyl form the instant claims reading on the ethyl form or a 2-methyl form there is a presumed expectation that the compounds possess similar properties, leading to the conclusion that the claims are obvious over Davis. Furthermore, Davis teaches a genus of compounds very similar to the instant claims and for the "control or prevention of inflammatory, immunological, bronchopulmonary, or cardiovascular disorders." Therefore, making an isomer or homolog of the species taught by Davis would have been obvious to one of ordinary skill in the art.

#### PREVIOUS CLAIM REJECTIONS

***Claim Rejections - 35 USC § 102***

1. Claims 31-36, 38-40, 43-46, 48-49, and 52 were rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al. (US 5,057,614).



The applicant's invention reads on the following species: 3-(1-indolyl)-4-(1-methyl-3-indolyl)-1H-pyrrole-2,5-dione

Davis et al. (US 5,057,614) on column 23, example 46 teaches the same compound, in addition the reference also teaches pharmaceutical compositions thereof in claim 11, for example.

Applicant argues that the added new matter proviso avoids the prior art. Because the added proviso avoids the prior art through anticipation, **the rejection is withdrawn.**

***Double Patenting***

2. The rejection of claims 50 and 51 is withdrawn because the claims were cancelled.

***Claim Rejections - 35 USC § 112***

Claims 31-36, 38-40, 42-46, and 48-52 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In view of the clarification provided by the applicant in combination with claim amendments, this ground of rejection is withdrawn.

***Claim Objections***

Claims 32-36, 38-40, 43-46, 48-49, and 52 are objected to for reading on a rejected base claim.

***Conclusion***

3. All claims are rejected. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ROBERT HAVLIN** whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

Art Unit: 1626

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626

/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626